

ORIGINAL ARTICLE

Assessment of the reporting of quality and outcome measures in hepatic resections: a call for 90-day reporting in all hepatectomy series

Michael E. Egger, Joanna M. Ohlendorf, Charles R. Scoggins, Kelly M. McMasters & Robert C. G. Martin II

The Hiram C. Polk Jr., MD Department of Surgery, University of Louisville, Louisville, KY, USA

Abstract

Background: The aim of this paper is to assess the current state of quality and outcomes measures being reported for hepatic resections in the recent literature.

Methods: Medline and PubMed databases were searched for English language articles published between 1 January 2002 and 30 April 2013. Two examiners reviewed each article and relevant citations for appropriateness of inclusion, which excluded papers of liver donor hepatic resections, repeat hepatectomies or meta-analyses. Data were extracted and summarized by two examiners for analysis.

Results: Fifty-five studies were identified with suitable reporting to assess peri-operative mortality in hepatic resections. In only 35% (19/55) of the studies was the follow-up time explicitly stated, and in 47% (26/55) of studies peri-operative mortality was limited to in-hospital or 30 days. The time period in which complications were captured was not explicitly stated in 19 out of 28 studies. The remaining studies only captured complications within 30 days of the index operation (8/28). There was a paucity of quality literature addressing truly patient-centred outcomes.

Conclusion: Quality outcomes after a hepatic resection are inconsistently reported in the literature. Quality outcome studies for a hepatectomy should report mortality and morbidity at a minimum of 90 days after surgery.

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Correspondence

Robert C. G. Martin II, Sam and Lolita Weakley Endowed Chair in Surgical Oncology, Professor of Surgery, Division of Surgical Oncology, Hiram C Polk Jr MD Department of Surgery, University of Louisville, 315 East Broadway, Suite 314, Louisville, KY 40202, USA. Tel.: +1 502 629 3355. Fax: +1 502 629 3030. E-mail: robert.martin@louisville.edu

Introduction

A hepatic resection has evolved into a common surgical procedure for a wide range of benign and malignant indications. The number of hepatic resections performed in the United States has been increasing over time.¹ Decreasing mortality rates for major hepatic resections have been reported over time.^{1,2} Despite the complexity of resections and the comorbidities of patients increasing, reported morbidity rates have remained relatively stable over time.^{2–4} While experience with complex hepatic resections has grown with favourable outcomes, more data are needed to risk stratify patients and

identify those at a high and low risk of post-operative complications in order to provide accurate and informed pre-operative counselling.

Patient-centred outcomes that look beyond short-term mortality and disease-free survival should be part of quality outcomes in a hepatic resection. Quality outcomes after a hepatic resection are inconsistently defined and variably reported in the literature. Benchmarks are being made based on outcomes data from a wide variety of sources, ranging from single institution centres to national administrative databases. The aim of this research was to review the most current decade of published outcomes after a hepatic resection, to identify and define robust quality and outcome parameters, and to propose a set of criteria for liver resection outcomes research in the future.

This study was presented at the Annual Meeting of the AHPBA, 19–23 February 2014, Miami, Florida.

Method

This systematic review was conducted in accordance with the PRISMA guidelines.⁵ An electronic search of Medline and PubMed databases was performed using combinations of the keywords 'quality outcomes,' 'hepatectomy,' 'liver resection' and 'hepatic resection.' The search was limited to studies published between 1 January 2002 and 30 April 2013. Inclusion criteria included studies focusing on resection for neoplastic disease with curative intent, although studies that integrated non-neoplastic or trauma indications along with malignant indications were reviewed. Exclusion criteria included non-English language publications, meta-analyses and series limited to living donor hepatectomies and repeat hepatectomies.

Two examiners reviewed all abstracts of studies identified for potential inclusion. Additional potential studies for inclusion were identified from the references of studies identified in the database search. Reviewers then compiled study characteristics and outcomes of interest, including study type (single centre, multi-institutional or administrative database), disease type, reported follow-up, extent of hepatic resection (major hepatectomy defined as ≥ 3 segments) and the time period of data collection. Outcomes of interest included mortality,

morbidity, major morbidity and post-operative liver failure; the various definitions of these outcomes were also recorded. Complications were considered defined if the explicit type of complications were reported and were considered graded if they were defined and ranked on an ordinal scale. Studies were then compared along the lines of reported mortality and morbidity outcomes.

Results

The results of the review process are reported in the Fig. 1. Reviewers identified 55 studies with suitable reporting to assess peri-operative mortality, and 28 studies with adequate reporting of peri-operative morbidity. The 55 studies reporting peri-operative mortality were heterogeneous in study population, design and outcome reporting. A meta-analysis of these reports with any meaningful statistical validity was not possible owing to heterogeneity. Study design and mortality measures are summarized in Table 1. Ranges of reported mortality rates were as follows: 0–11.9% (30 day), 3.4–9.1% (60 day, and 0.9–10.8% (90 day). Study characteristics of the 28 studies reporting peri-operative morbidity after hepatic resection are

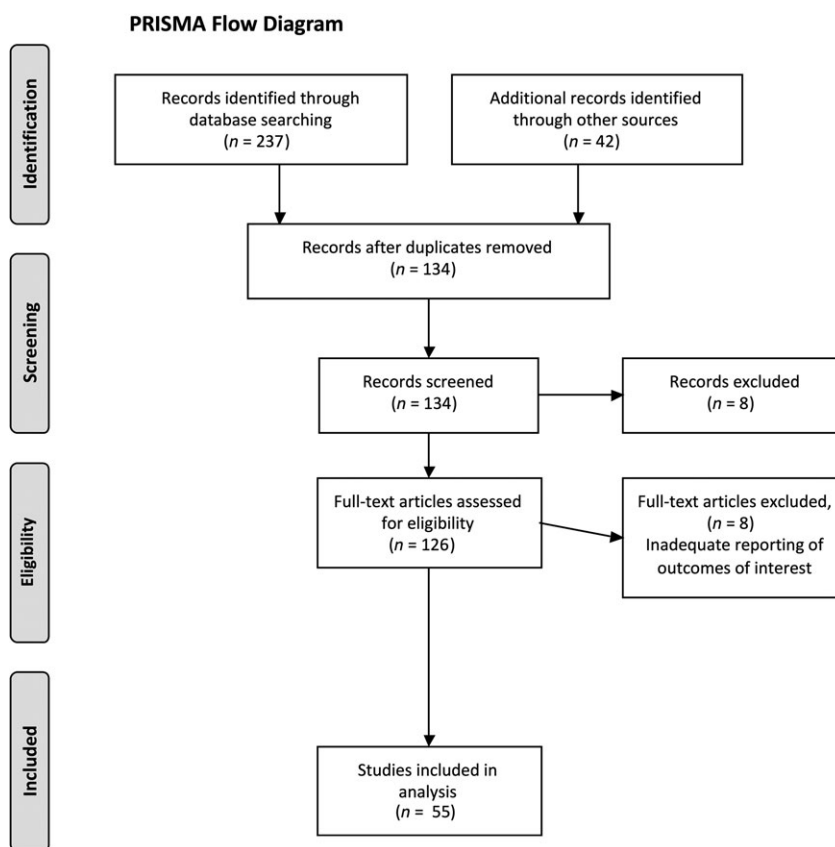


Figure 1 Flow diagram illustrating the selection of studies in the review process

Table 1 Summary of hepatic resection study design parameters reporting peri-operative mortality outcomes^{1–4,6,8–11,19–25,27,31,37–73}

Data Source	
Large Administrative Database	26/55 (47%)
Multi-centre	5/55 (9%)
Single-centre	24/55 (44%)
Follow-Up Time Reported	19/55 (35%)
Time Period for Mortality	
Strictly In-hospital	11/55 (20%)
30 day	15/55 (27%)
60 day	2/55 (4%)
90 day	17/55 (31%)
Not Defined	10/55 (18%)

Table 2 Summary of hepatic resection study design parameters reporting peri-operative morbidity outcomes^{2–4,10,11,19,22,23,25,27,38,41–43,45–48,51,52,54,55,58,62,63,69,71,73}

Data Source	
Large Administrative Database	10/28
Multi-centre	2/28
Single-centre	16/28
Diseases Reported	
Both Benign and Malignant Diseases	19/28
Hepatocellular Carcinoma Only	5/28
Colorectal Liver Metastases Only	4/28
Follow-Up Time Reported	14/28
Time Period For Morbidity	
30 day	8/28
90 day	1/28
Not Defined	19/28
Complication Classification	
Not graded, but clearly defined	17/28
Graded (Clavien–Dindo type) ²⁸	7/28
Neither graded nor defined	4/28
Independent Assessment of Complications	10/28

summarized in Table 2. Significant heterogeneity in study design precluded any meaningful meta-analysis of the published findings, especially with regard to the definition of post-operative liver insufficiency. The most commonly reported definition of post-operative liver insufficiency is a post-operative peak total bilirubin > 7 mg/dl (Table 3).

There was a paucity of studies addressing patient-centred outcomes beyond peri-operative mortality and classic surgical complications. Few studies focused specifically on length of stay and readmission rates in exclusive hepatic resection populations. Length of stay appears to be decreasing over time after a hepatic resection.^{1,6} In two studies that examined risk factors

Table 3 Summary of hepatic resection study design parameters reporting post-operative liver insufficiency^{2,4,11,19,22,25,38,40,47,60,62,72,73}

Data Source	
Large Administrative Database	0/13
Multi-centre	2/13
Single-centre	11/13
Disease	
Benign and Malignant	8/13
HCC Only	2/13
CRLM Only	3/13
Liver Insufficiency Definition	
'50-50 Criteria' ³⁷	2/13
Peak Total bilirubin > 7 mg/dl	6/13
Other	5/13

HCC, hepatocellular carcinoma; CRLM, colorectal liver metastases.

for readmission after complex surgery, including hepatic resections, pre-operative sepsis, American Society of Anesthesiologists class, the presence of an open wound, post-operative complications, increased age, decreased oral intake and an increased number of discharge medications, were all associated with an increased risk of readmission.^{7,8} Several studies were identified that addressed survey-based quality of life outcomes after hepatic resection.^{9–14} After hepatic resection, patient-reported quality of life indicators appear to return to baseline or improve on the order of 3–6 months after operation, with some reporting delays in return to baseline approaching 12 months.^{9,11,12,14} Questionnaires have been developed and validated that are specific to patient-reported outcomes after hepatic resections.^{15,16}

Discussion

The findings in this study reveal a great deal of heterogeneity of quality outcomes and reporting parameters for studies describing patients undergoing a hepatic resection. Even the seemingly straightforward measure of peri-operative mortality is reported over a wide range of time (i.e. 30, 60 or 90 days) that limits the ability to compare risk factors and interventions across studies. Morbidities are also reported over a range of post-operative times and are inconsistently defined and graded. Follow-up is often not explicitly stated in reports. Finally, patient- and oncological-centred outcomes are not widely reported, thus the definition of 'quality' outcomes after a hepatic resection is difficult to capture by reviewing the literature.

Traditional 30-day mortality is no longer considered an appropriate length of time to capture the true mortality related to an operative hepatic resection. A significant number of deaths related to liver failure and other complications from surgery occur after the traditional 30-day post-operative

period.^{17–20} The magnitude of this effect is sizable and consistent across multiple indications for hepatic resection, including hepatocellular carcinoma and colorectal liver metastases (CRLM), with most studies reporting an approximate doubling of mortality rates from 30 to 90 days post-operatively.^{19–21} Whether this increase in mortality is simply a function of a larger time frame in which to capture events or an accurate reflection of true surgery-associated mortality is a question that can only be answered with further well-designed studies.

While there is less evidence that peri-operative morbidity rates would likewise increase from 30 to 90 days post-operatively, it is certainly logical to assume that there are a significant number of complications that are under reported by traditional 30-day studies. A lack of follow-up beyond 30 days is the critical shortcoming of the use of large administrative databases to capture and report quality outcomes after hepatic surgery. This inherent limitation will limit the use of such large databases to draw meaningful conclusions regarding risk factors for poor peri-operative outcomes, unless databases are integrated and analysed as such to allow reporting of 90-day outcomes. Until then, collaborative efforts between multiple high volume centres will be the best opportunity to perform appropriate assessment of risk factors for poor quality outcomes in hepatic surgery. Based on the mounting recent evidence, it is clear that peri-operative mortality and morbidity after a hepatic resection should be reported within the 90-day operative period.

Peri-operative morbidity is substantial after major hepatic resections. Morbidity rates (reported from 30 to 90 days post-operatively) range from 14% to 55%.^{2,3,22–27} Complications are much more difficult to define and compare across different studies from different institutions. The commonly used Clavien–Dindo classification of post-operative complications is a validated measure of the severity of post-operative complications with a wide range of applications across surgical specialties.²⁸ While this classification is easily assessed and reportable, most of the studies reviewed did not classify complications in a graded fashion; only 25% of studies reviewed used the Clavien–Dindo classification system. Independent assessment of peri-operative complications is preferred compared with provider assessment to reduce potential bias in under-reporting of complications. Post-operative liver insufficiency is another potential measure of quality outcomes after a hepatic resection. The definition of post-operative liver insufficiency is variable (Table 3). The most common measure reported in this review, defined as a post-operative peak in total bilirubin > 7 mg/dl, is a reliable, objective and easily measured parameter that is the preferred measurement to use when reporting outcomes after hepatic resection. A peak postoperative total bilirubin > 7 mg/dl is associated with increased morbidity and mortality.¹⁹ Rahbari *et al.*²⁹ have summarized the relevant literature regarding assessment of post-hepatectomy liver failure in an effort to reach a consensus definition. The definition proposed in the

consensus statement focuses on the assessment of the impact of clinical management and an assessment of synthetic function by abnormal laboratory values. While this definition is reasonably simple and easily applied, there remains some degree in subjectivity regarding the assessment of the impact on clinical management. Absolute total bilirubin is proposed as an even more simplified measure of post-operative liver dysfunction, as it is easily reproducible, routinely measured and is objective. Post-operative hyperbilirubinaemia is also associated with an increased risk of readmission after a major hepatectomy, thus the routine reporting and assessment of post-operative total bilirubin levels may provide more opportunities for quality and outcomes assessment.³⁰

Novel patient-centred outcome measures are needed to assess quality results after a hepatic resection that go beyond traditional measures of operative morbidity. In an age of increasing scrutiny of health care resource utilization, readmission rates are an important metric that may capture both surgeon and system factors related to quality. More patients are being discharged to places other than home after a hepatic resection.³¹ The rate of readmission within 90 days after a hepatic resection may approach 15%.³² Recently, in a series of 266 general surgical oncology patients, risk factors for 90-day readmission included age ≥ 69 years, ≥ 9 medications at discharge, poor oral intake and discharge home with a home health agency.⁷ These risk factors and others need to be further evaluated in larger series of exclusively hepatic resection patients to define areas for improvement that may reduce readmission rates and improve health care resource utilization. These types of granular, patient-specific factors are difficult to capture in large administrative databases based on claims data, therefore, multi-institutional series will have to lead the way in these efforts.

Peri-operative complications have been associated with worse oncological outcomes after a hepatic resection for CRLM.³³ An uncomplicated post-operative course is critical for the patient undergoing a hepatic resection for malignancy, particularly when an up-front hepatic resection is being performed without neoadjuvant therapy for CRLM. Complications have been associated with a delay in initiation of post-operative chemotherapy, whereas lack of adjuvant therapy has been shown to be an independent risk factor for worse survival after a up-front hepatic resection.^{33,34} For these reasons, studies reporting outcomes after hepatic resections for malignancies should report the success rate of timely initiation of adjuvant systemic chemotherapy, when oncologically appropriate, as a global outcome measure that can capture undesirable irregularities in a patient's post-operative course.

A recent review reported similar findings to this study, again emphasizing the heterogeneity of reporting of outcomes and risk factors in hepatic resection publications.³⁵ This report highlights the lack of relevant patient-reported outcomes in the literature and how poorly defined morbidity outcomes are in current hepatic resection studies.

Regarding quality of life instruments, the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire –C30 (EORTC –Q30) is a well-studied, validated instrument that has been used to assess outcomes after liver resection for colorectal metastases.¹¹ The Short-Form-12 Health Survey and the Functional Assessment of Cancer Therapy Hepatobiliary (FACT-Hep) has also been used to assess outcomes after a liver resection.^{10,35} No one measure has been shown to be superior to another. There are currently a wide variety of validated instruments for researchers to use to assess quality of life after a hepatic resection, although further study is needed to assess the optimal instruments to use for outcomes reporting.

The findings of this review need to be interpreted with the study limitations in mind. Certainly, as described by Lim *et al.*³⁶, there is a high risk of bias in the publication and reporting of results. The search strategy may have missed relevant articles, and the limiting of the review to the most recent decade may have omitted relevant, high-quality studies. There is certainly a high degree of heterogeneity in the reporting of outcomes across studies, which limits the feasibility of meta-analysis techniques to summarize outcomes and relevant risk factors in a meaningful way. Lim *et al.* made concerted efforts to summarize and quantitatively estimate the effects of multiple risk factors on outcomes in the literature.³⁶ This work instead focused on a more qualitative assessment of the current state of outcomes reporting in hepatic resection literature. This assessment is the rationale behind our proposed reporting criteria.

Based on the findings of the present study, a set of criteria are proposed which future studies of quality outcomes after a hepatic resection should try to achieve to improve the consistency and quality of outcomes reporting in hepatic surgery:

- 1 Peri-operative mortality should be reported within the 90-day post-operative period
- 2 Peri-operative morbidity should be reported within the 90-day post-operative period
- 3 Peri-operative complications should be graded in a standard fashion
- 4 Complications should be assessed by an independent observer when possible
- 5 Post-operative liver insufficiency, when reported, should be defined as a peak in post-operative total bilirubin > 7 mg/dl
- 6 When oncologically appropriate, timely initiation of adjuvant chemotherapy after hepatic resection for malignancy should be reported
- 7 Patient-reported quality-of-life outcomes should be assessed when possible by validated instruments

Currently, most of the studies in the literature reporting outcomes after a hepatic resection do not meet these criteria (Tables 1–3). These measures are proposed in an effort to raise the quality of outcomes reporting and improve the comparability of study findings across a variety of institutional settings.

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Conflict of interest

None declared.

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